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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/638,989

08/11/2003

Robert Greenberg

S230-USA

6557

28284

7590

04/27/2009

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EXAMINER

DIETRICH, JOSEPH M

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

04/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/638,989	Applicant(s) GREENBERG ET AL.	
	Examiner Joseph M. Dietrich	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/3/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed January 27, 2009 have been fully considered but they are not persuasive.

Applicant argues that the present invention describes a method of forming insulating layers comprising parylene whereas the layers in the implant disclosed by Berrang comprise fluoropolymer. Claim 1 is an apparatus claim, thus the steps used to form the insulating layers are not relevant to the claims. Furthermore, because claim 1 is a comprising claim, it is not limited to only parylene, but may also comprise other materials since "comprising" is open-ended. Please see MPEP 2111.03.

Applicant argues that since the use of parylene has hitherto been limited to only that of a biocompatible coating material for implants, it would not have been obvious to one of ordinary skill in the art to use parylene in an implantable electrical circuit. It must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the present case, because Parylene is a well known biocompatible insulator, it would have been obvious to modify the insulation layers as taught by Berrang with Parylene (or polyparaxylylene) insulation layers.

Also, Berrang does teach that Parlyene can be used as a protective coating. Thus, both layers would necessarily comprise Parylene.

Claim Objections

2. Claim 2 is objected to because of the following informalities:

Claim 2 contains the trademark/trade name Parylene. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a polyparaxylylene and, accordingly, the identification/description is indefinite.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1 – 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berrang et al. (U.S. Patent Application Publication 2003/0109903).

Regarding **claims 1 – 8 and 12 – 14**, Berrang discloses a first insulation layer (e.g. 11 in Fig. 1); a second insulation layer that defines at least one aperture (e.g. 14) exposing an electrical, biocompatible conductor comprised of titanium (e.g. 13 and paragraph 53); said conductor located between the two insulation layers (e.g. Fig. 1); and at least one other polymer layer that is either located between the first insulation layer and the conductor (e.g. 12) or not in between the two insulation layers (e.g. 10); but fails to disclose specifically that the two insulation layers are comprised of polyparaxylylene (and more specifically Parylene) and the other polymer layers are comprised of polyimide. However Berrang teaches that both Parylene and polyimide can be used as biocompatible insulation as set forth in paragraphs 1 and 80. Furthermore both materials are well known in the art as biocompatible insulation. It would have been obvious to modify insulation layers (11 and 14) and polymer layers (10

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and 12) as taught by Berrang with Parylene and polyimide, respectively, since such a modification would provide the predictable results of optimizing the insulation properties of the device surrounding a conductor.

Regarding **claims 9 – 11**, the phrases “suitable for stimulating a nerve,” “suitable for sensing a signal from a nerve,” and “suitable for detecting or transmitting signals to living tissue” are functional language. The conductor as taught by Berrang is capable of performing these functions as it is titanium and allows an electrical current to travel through it.

6. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berrang et al. as applied to claim 14 above, and further in view of Strandberg et al. (U.S. Patent 5,476,496).

Regarding **claim 15**, Berrang discloses the claimed invention except for titanium nitride. Strandberg teaches that it is known to use titanium nitride as a biocompatible coating as set forth in column 4, lines 35 – 39. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coating as taught by Berrang with the titanium nitride coating as taught by Strandberg, since such a modification would provide the predictable results of providing a flexible layer around the entire device that is safe and effective for implantation in the body.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph M. Dietrich whose telephone number is (571)270-1895. The examiner can normally be reached on M-F, 8:00 - 5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. D./
Examiner, Art Unit 3762
4/21/09

/George R Evanisko/
Primary Examiner, Art Unit 3762